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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	McGLYNN, Paul
	:	BAKALE, Roger
	:	STURGE, Craig
Serial No.	:	10/728,873
Filing Date	:	December 8, 2003
For	:	LEVALBUTEROL SALT
Art Unit	:	1616
Examiner	:	GOLLAMUDI, Sharmila S.
Confirm No.	:	1167
Docket No.	:	00324/US1
Customer No.	:	024330

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

UNITED STATES

Sir:

SUPPLEMENTARY INFORMATION DISCLOSURE STATEMENT

As a means of complying with the duty of disclosure, Applicant's herewith submit a Supplementary "Information Disclosure Statement by Applicant" on PTO Form PTO/SB/08A for consideration by the Examiner. It is believed that this

statement is being submitted in accordance with 37 C.F.R. § 1.97(b)(3), before the mailing of a first Office action on the merits, and hence that no fee is due for this submission. If this is incorrect, the Commissioner is authorized to debit any fee falling due from Deposit Account NO. 50-1230 (Martin A Hay & Co).

The references were cited in the search report drawn up by the European Patent Office on the corresponding international patent application. A copy of this search report is attached.

One of the references is a Chinese patent specification, CN1382685, which was published on December 4, 2002. A translation of the Chinese patent specification is also enclosed. The Chinese patent specification discloses levalbuterol L-tartate as an intermediate in the resolution of racemic albuterol.

Applicants would also like to provide the Examiner the following background information:

BACKGROUND INFORMATION

Applicants would like to provide the Examiner with the following background information relating to the present application.

The present application seeks patent protection for technology invented in the course of the development of a metered dose inhaler product for delivering R-albuterol (levalbuterol) by inhalation. The inhaler contains a propellant and crystals of levalbuterol L-tartrate as the hemitartrate.

Prior to the filing date of the provisional application from which the present application claims priority

under 35 U.S.C. 119, the performance of the metered dose inhaler (MDI) product was evaluated in clinical trials under the control of Sepracor, Inc, the assignee of the rights in the present application.

Details of the clinical trials conducted on the metered dose inhaler product prior to the filing date of the present application are as follows:-

A confidential brochure for clinical investigators, who would conduct clinical trials of the MDI product, was prepared on June 29, 2001. It was then given to investigators. The information contained in the brochure, which included the identity of the active ingredient, levalbuterol L-tartrate, was thus provided to the investigators in confidence.

Two clinical trials of the MDI product were conducted by the investigators, as follows:-

First Trial

Conducted October 16, 2001 to March 22, 2002.

The purpose of this trial was to compare the efficacy of two doses of levalbuterol L-tartrate in the reversal of bronchoconstriction in adults relative to a placebo and racemic albuterol sulfate.

162 adults across 29 centers in the USA were given a metered dose inhaler containing a placebo, racemic albuterol sulfate, levalbuterol L-tartrate (dose 45μg) or levalbuterol L-tartrate (dose 90μg). The adults were not told what was in the MDI they were given. They were asked to use the MDI for 4 weeks and to record the performance of the MDI in the treatment of bronchoconstriction. After the trial had been completed, their records were collected and analyzed. The results of the trial were unblinded on May 2, 2002.

Second Trial

Conducted October 24, 2001 to July 23, 2002.

The purpose of this trial was to compare the efficacy of two doses of levalbuterol L-tartrate in the reversal of bronchoconstriction in children relative to a placebo and racemic albuterol sulfate.

127 children across 21 centers in the USA were given a metered dose inhaler containing a placebo, racemic albuterol sulfate, levalbuterol L-tartrate (dose 45µg) or levalbuterol L-tartrate (dose 90µg). The children were not told what was in the MDI they were given. They were asked to use the MDI for 3 weeks and to record the performance of the MDI in the treatment of bronchoconstriction. After the trial had been completed, their records were collected and analyzed. The results of the trial were unblinded on October 4, 2002.

On January 7, 2002, a press release was issued by Sepracor, Inc and 3M Drug Delivery Systems (DDS) Division announcing the "initiation of a scale-up and manufacturing collaboration for a Xopenex (levalbuterol tartrate) hydrofluoroalkane (HFA) metered-dose inhaler (MDI)". A copy of the press release is attached.

The provisional application from which the present application claims benefit was filed on December 10, 2002, within one year of the issue of the press release, the unblinding of the clinical trial results and the publication of the Chinese patent specification, CN1382685, but more than one year after the clinical trials commenced.

If the Examiner considers that he or she needs any further information about the conditions under which the

clinical trials were conducted, the Examiner is kindly requested to contact the undersigned.

COMMUNICATION BY TELEPHONE

The undersigned's office is located in the United Kingdom, and hence the Examiner may have difficulty contacting him from the USPTO by telephone. If the Examiner wishes to speak with the undersigned by telephone, he or she can contact the undersigned by e-mail at martinahay@martin-a-hay.com.

Respectfully submitted,

Hay, Martin Alexander
Agent for Applicants
Registration No. 39,459
Phone: 011 44 1625 500057
e-mail: martinahay@martin-a-hay.com

Customer No. 024330
[Martin A. Hay & Co.,
13 Queen Victoria Street
Macclesfield
Cheshire
SK11 6LP
UNITED KINGDOM]

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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Complete if Known	
Application Number	10/728,873
Filing Date	December 08, 2003
First Named Inventor	McGLYNN, Paul
Art Unit	
Examiner Name	
Attorney Docket Number	00324/US1

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A4	US- 5399765	03.21.1995	Framingham et al	
	A5	US- 5225183	07.06.1993	Purewal et al	
		US-			
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	B1	CN1382685A	12.04.2002	Chengdu Org.Chem.Inc		✓
	B2	WO 96/32099	10.17.1996	Glaxo Wellcome Inc		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.